

# MIXING AND DISTRIBUTION DEVICE FOR FIXING PASTE, PARTICULARLY FOR MULTICOMPONENT BONE CEMENT

## Technical Field

The present invention relates to a mixing and distribution device for  
5 fixing paste, particularly for multicomponent bone cement.

## Background Art

Adhesives, adhesive pastes and fixing pastes in general are currently  
used in many fields to mutually fix two parts. These products are often  
produced by mixing two different components, which form the final product  
10 by reacting.

The use of these products can cause several problems, such as for  
example the release of toxic gases during mixing, rapid drying of the  
product once it has formed, difficulty in applying it to the parts to be  
bonded, et cetera.

15 One of the fields in which the use of this product is particularly  
delicate is orthopedic surgery.

In this field it is in fact necessary to replace certain bone components,  
such as for example the head of the femur and/or the cotyloid cavity that  
engages the head in the pelvis, with artificial prostheses made of the most  
20 disparate materials, especially metallic ones, but also plastic materials or  
materials derived from ceramic (for example porcelain).

Alongside the problem of replacement, there is the fundamental need  
to fix said artificial prostheses as rigidly as possible to the reference bone.

Substantially two approaches are used to achieve this fixation.

25 The first approach implies coupling the prosthesis to the reference  
bone by way of mechanical connections such as screws, cerclages, et cetera,  
while the second approach, which is the one most widely used at present,  
provides for adhesive fixing elements.

This second approach is always used in any case when, after a certain  
30 time, the mechanical connections fail without the possibility of restoring

them or replacing them with other mechanical fixations.

As regards this second approach, an acrylic-based cement is predominantly used at present.

The acrylic cement currently used is obtained from the combination  
5 of two components: one in powder form (usually a polymethyl methacrylate) and one in liquid form (usually a methyl or butyl methacrylate or a combination thereof), in specific proportions, which are placed in mutual contact.

The preparation and subsequent use of this cement, however, has  
10 drawbacks.

Combining these two components in fact currently entails some problems in use.

First of all, this combination produces a chemical reaction that generates toxic and carcinogenic vapors.

15 Further, the mixing of these two components must occur in relatively short times in order to avoid the drying reaction.

Moreover, mixing must occur so that no air (or gas) bubbles form inside, since said bubbles, once in place, reduce the mechanical strength of the cement and can also cause contaminations and infections.

20 Secondly, the cement obtained from this combination must sometimes be introduced in cavities that are difficult to fill, with the risk of leaving residual regions without cement, with an obvious reduction in mechanical strength.

Currently, all the devices used to mix these components and distribute  
25 the cement in the affected region have a common structure and operating principle.

Basically, these devices comprise a container in which the two components whose combination will produce the cement are introduced by means of various methods.

30 A piston or other variously shaped element, connected to the outside

and closed by means of sealing gaskets, is arranged inside said container.

A more or less high vacuum can be produced inside the container by using a conventional manual or electric suction pump.

Once almost all the air is eliminated (if suction is used), the rotary or pressing motion of said piston produces the mixing of the two components.

In this manner, the resulting toxic gas is not dispersed into the environment; moreover, fewer bubbles are present in the compound because mixing occurs almost in the absence of air.

Once this step has ended, the container is usually opened (although there are rather complicated and expensive "closed cycle" solutions) in order to remove the internal piston and collect the resulting cement paste.

This operation can be performed in several manners, including manual gathering of the cement paste, manipulating it so as to obtain the intended consistency and shape, and then inserting it in the bone cavity.

As an alternative, it is possible to pour the paste, if it is left liquid enough, directly into the bone cavity by means of the container itself.

Moreover, it is possible to insert a piston in the container, converting it into a syringe and making the cement paste flow out through a nozzle arranged at the base of the container into the bone cavity to be filled.

These devices in any case have various drawbacks in different respects.

One of these drawbacks is that one is normally forced to reopen the container, thus releasing into the environment the residual gas generated during the mixing of the two components.

Moreover, when the mixing element (for example a rotating spatula) that is present inside the container is extracted in order to draw the paste from the container, it carries away part of the paste that remains attached to it.

Further, using these devices requires several manual operations that are often difficult and time-consuming and are always rather laborious.

Another drawback is the complexity and size of the elements that compose these devices, which do not allow easy and immediately understandable use on the part of nursing staff and of the physician who must position and introduce the cement in the cavity.

5       The problem of the release of the gas produced by the combination of the two components of the cement is solved by the previously mentioned "closed cycle" devices, but these devices are very complicated, almost always bulky, and expensive.

10       The complexity of these devices does not allow their economically convenient disposable use, which is an increasingly required characteristic for surgical instruments in order to avoid the sterilization costs and the unavoidable possible residual risks of transmission of infectious diseases.

15       One solution that substantially solves the problems noted earlier is disclosed in Italian patent application No. PD 2002 A 284 filed by this same Applicant.

20       This application discloses a mixing and distribution device for multicomponent bone cement that comprises a box-like body that forms inside it a cylindrical receptacle that is closed in an upper region by a removable fluid-tight lid and inside which a mixing/distribution screw feeder is accommodated.

A piston is coaxially arranged between the screw feeder and the lid and is associated with movement means. Said piston forms, inside the receptacle, on opposite sides with respect to its ends, a venting chamber toward the lid and a mixing chamber toward the bottom of the receptacle.

25       The mixing chamber and the venting chamber are connected respectively to a channel for distributing bone cement, which is controlled by first valve means, such as a plug valve, and to a venting channel, which is controlled by second valve means, such as a second plug valve.

30       The venting channel and the distribution channel can be associated functionally with means for producing vacuum, such as a vacuum pump.

The screw feeder can be associated with rotation means, such as an electric motor, by way of fixing lugs.

The vacuum pump allows to draw air and gas from the receptacle during the various steps for mixing and distributing the cement.

5 With this device there is no leakage or escape of toxic gas during the mixing of the components of the cement or in the subsequent steps, since any gas is aspirated continuously. The mixture is thus obtained in a practically airless environment, thus avoiding the formation of bubbles of air or gas.

10 All the resulting cement is used, since the rotation and thrust of the screw feeder tend to propel it out until it is depleted.

The unused fraction of cement, once the valves have closed again, can be left inside the box-like body and can be eliminated together with the container without producing environmental contamination.

15 Although this device solves most of the problems of known types, it is not free from drawbacks.

An important characteristic of these devices is that it must be possible for the health worker who uses them to handle them with a single hand during distribution of the cement paste on the part to be fixed; the other  
20 hand is in fact often busy with other surgical instruments.

The described device instead cannot be handled easily with a single hand, and this makes it awkward to use.

#### Disclosure of the Invention

The aim of the present invention is to provide a mixing and  
25 distribution device for fixing paste, particularly for multicomponent bone cement, that solves the drawbacks noted in known types.

Within this aim, an object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, that works without loss or leakage of the gas  
30 generated by the mixing of the components of the cement and allows to

extract the air from the container in which mixing occurs.

Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, that can be handled with a single hand during distribution of the  
5 fixing paste.

Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, in which the cement can flow out in a controlled and precise manner.

10 Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, in which the components are mixed without producing air bubbles.

Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone  
15 cement, that is simple and compact, easy to use, and has a limited number of essential components.

Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, that can be used disposably.

20 Another object of the present invention is to provide a mixing and distribution device for fixing paste, particularly for multicomponent bone cement, that can be produced by way of known systems and technologies.

This aim and these and other objects that will become better apparent hereinafter are achieved by a mixing and distribution device for fixing paste,  
25 particularly for multicomponent bone cement, comprising a box-like body that forms internally a receptacle that is closed in an upper region by a detachable and substantially fluid-tight lid, inside which means for mixing the components of the fixing paste are accommodated, said mixing means being coupled to a piston that forms, inside said receptacle, a venting  
30 chamber toward said lid and a mixing chamber toward the bottom of said

receptacle, said mixing chamber being connected to a channel for distributing bone cement, which is controlled by valve means, said venting chamber being instead connected to a venting channel, which can be functionally associated with suction means, said device being characterized  
5 in that said mixing means are constituted by longitudinally elongated mixing blades that are arranged so as to slide within complementary through slots formed in said piston, a rotation pivot being further locked coaxially on said piston and being arranged so that it can slide through a corresponding fluid-tight hole formed in said lid, said rotation pivot being  
10 associable with corresponding rotation means that can be operated by a user during the mixing of the multicomponent paste, said device further comprising a handgrip for a single hand of the user, with which means for the translational motion of said rotation pivot together with said piston toward the bottom of said receptacle are associated, said means being  
15 actuatable with the same hand associated with said handgrip, said venting and mixing chambers being mutually connected for the passage of gaseous fluids.

#### Brief Description of the Drawings

Further characteristics and advantages of the present invention will  
20 become better apparent from the following detailed description of a preferred but not exclusive embodiment thereof, illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a perspective view of the device according to the invention in the configuration for mixing the components of the  
25 multicomponent paste;

Figure 2 is an exploded view of the device according to the invention;

Figure 3 is a front sectional view of the device according to the invention;

Figure 4 is a perspective view of the device according to the  
30 invention, divided into two separate preassembled parts;

Figure 5 is a perspective view of the device according to the invention in the configuration for distributing the multicomponent paste.

#### Ways of carrying out the Invention

With reference to the figures, a mixing and distribution device for  
5 fixing paste, particularly for multicomponent bone cement, according to the invention, is generally designated by the reference numeral 10.

The device 10 comprises a preferably cylindrical box-like body 11, which forms internally a cylindrical receptacle 12.

The cylindrical receptacle 12 is closed in an upper region by a  
10 detachable and substantially fluid-tight lid 13.

The lid 13 is internally cylindrical, with an inside diameter that has substantially the same dimensions as the outside diameter of the box-like body 11.

Externally, the lid 13 is preferably cylindrical (but it can also be for  
15 example polygonal).

Means 14 for detachable fixing to the box-like body 11 protrude from the rim of the lid 13; the fixing means 14 consist of teeth 15 of the snap-fit type, which enter by elastic deformation corresponding locking cavities 16 formed through a perimetric annular tab 17 that protrudes laterally from the  
20 cylindrical body 11.

Means 18 for mixing the components of the fixing paste, described hereinafter, are accommodated inside the cylindrical receptacle 12.

The mixing means 18 are rigidly coupled to a piston 19, which forms, inside the receptacle 12, a venting chamber (not shown in the figures, since  
25 the piston 19 is shown at the beginning of its stroke) toward the lid 13 and a mixing chamber 21 toward the bottom of the receptacle 12.

The volume of the two chambers can obviously vary according to the axial position occupied by the piston 19 inside the receptacle 12, as will become better apparent hereinafter.

30 The piston 19 has a first cylindrical portion 22, whose outside



diameter is substantially equal to (at most slightly smaller than) the diameter of the receptacle 12, and a second portion 22a, which has a conical shape toward the bottom of the receptacle 12.

In an alternative embodiment, not shown in the figures, the vertex  
5 region of the second conical portion 22a has a coaxial protrusion that is substantially elongated downward.

A rotation pivot 24 is locked coaxially on the piston 19 by way of corresponding locking means 23 and is arranged so that it can slide through a corresponding substantially fluid-tight hole 25 formed in the lid 13.

10 The locking means 23 comprise a first shank 26, which preferably has a hexagonal cross-section and is formed at one end of the pivot 24; two studs 27 protrude on opposite sides from its lateral surface.

A seat 28 shaped complementarily to the first shank 26 is formed axially on the piston 19, and two openings 29 complementary to the two  
15 studs 27 are formed on its side walls; mutual coupling occurs by elastic deformation of the walls of the seat 28.

The rotation pivot 24 can be coupled to corresponding rotation means 30, which can be actuated by a user during the mixing of the multicomponent paste.

20 The rotation means 30 are constituted for example by a crank 31, which is detachably coupled to the free end of the pivot 24.

The free end of the pivot 24 is constituted by a second shank 32, which preferably has a hexagonal cross-section.

As an alternative, the means for rotating the pivot 24 can be  
25 constituted for example by an electric motor or, as an alternative, by a pneumatic motor (both of which are not shown in the figures), which are present in operating rooms (electric power supplies and pneumatic power supplies are in fact both present in operating rooms) when the device is used; a chuck for coupling to the second shank 32 is associable with said  
30 motors.

The venting chamber is connected to a venting channel 33, which can be functionally associated with suction means (not shown in the figures), such as for example a vacuum pump.

The venting channel 33 is constituted for example by a tube 34 that  
5 protrudes from the upper portion of the lid 13.

The mixing chamber 21 is connected to a channel 35 for distributing the bone cement toward the outside of the box-like container 11.

The distribution channel 35 protrudes from the bottom of the receptacle 12, which has a conical shape, by means of a nozzle 36 controlled  
10 by valve means 37, such as for example a plug valve 38.

The device 10 further comprises a handgrip 40 for one hand of a user during the distribution of the multicomponent paste.

The handgrip is constituted for example by a pistol grip 41, which is rigidly coupled to the lid 13.

15 In this embodiment of the invention, the pistol grip 41 is monolithic with the lid 13, but in alternative embodiments it is possible to use handgrips that are detachable with respect to the lid 13 (or can be optionally detached with respect to the box-like body 11).

Means 43 for producing the translational motion of the rotation pivot  
20 24 (with the piston 19 rigidly coupled thereto), toward the bottom of the receptacle 12 are associated with the handgrip 40.

The translational motion means 43 are constituted, in this embodiment, by a ratchet-type mechanism, which is constituted by a plurality of annular bulges 45 that have a sawtooth transverse profile (in  
25 which the inclination of the teeth converges toward the lid 13) and are engaged by two complementarily shaped teeth 46 arranged monolithically on the first end of a first-class (centrally-pivoted) lever 47.

Elastic return means 49 that act between the lever 47 and the pistol grip 41 are provided between the fulcrum and the second end of the lever  
30 47.

In particular, the elastic return means 49 are constituted by an elastically deformable leaf-spring element 50, which cantilevers out from the second end of the lever 47 toward said first end and abuts against the bottom of the pistol grip 41.

5 A collar 51 is provided on the lid 13, and the fluid-tight hole 25 is formed coaxially to the collar.

Tabs 52 for preventing reversibility of the translational motion (toward the bottom of the container 11) of the pivot 24 are provided on the collar 51; the tabs 52 are elastically deformable and are provided with teeth  
10 that are shaped complementarily with respect to the annular bulges 45 of the pivot 24, so as to prevent the accidental upward motion of the pivot 24.

A retention element 55 is associated with the pivot 24 and has a C-shaped part designed to be coupled reversibly, by elastic deformation, to an annular groove 54 that is formed on the pivot 24 at the beginning of the  
15 annular bulges 45 and is directed toward the first shank 26.

The retention element 55 is coupled to the annular groove 54 only during the mixing of the multicomponent paste.

Proximate to the first shank 26 there is also an annular pocket (not shown in the figures) for accommodating a corresponding sealing gasket.

20 The mixing means 18 are constituted for example by mixing blades 57, which are predominantly longitudinally elongated and are arranged so as to slide inside complementary slots 58 formed in the piston 19.

The length of the mixing blades 57 is preferably equal to the internal length of the receptacle 12, and their transverse profile is curved in this  
25 embodiment, but other profiles can be used, also depending on the type of multicomponent paste to be mixed; the thickness of the mixing blades 57 is substantially constant, but in alternative embodiments it is also possible to use blades that have a variable thickness, for example a thickness that increases from the side of the container 11 toward the pusher piston 24.

30 The end of the mixing blades 57 that is directed toward the lid 13 has

a head 59 that is wider than the complementary slots 58.

The coupling of the mixing blades 57 to the slots 58 is provided with small passages (not shown in the figures) for the outflow of the air and gas from the mixing chamber 21 to the venting chamber.

5       Circumferential pockets 60 for accommodating corresponding scraper rings 61 for the side wall of the receptacle 12, or alternatively sealing gaskets (not shown in the figures), are provided on the first cylindrical portion 22 of the piston 19.

Advantageously, the device comprises accessories, such as a stand 62  
10   in which it is possible to insert the box-like container 11, so that it is directed downward, in order to mix the multicomponent paste, and a collar-funnel 63 to be arranged in abutment against the annular tab 17 and is useful during the pouring of the components of the multicomponent paste.

Moreover, the present invention comprises an extension nozzle 64 to  
15   be fixed to the nozzle 36, of the syringe-needle type, so as to precisely direct the paste during distribution on the parts to be fixed.

The invention is preferably entirely made of plastics.

The operation of the device according to the invention is as follows.

The container 11 is positioned on the stand 62 and the collar-funnel  
20   63 is fitted.

At this point, the components of the paste are poured, the collar-funnel 63 is removed, and the assembly constituted by the lid 13, with the pivot 24 at the beginning of its stroke with respect to the hole 25 and the piston 19 adjacent to the lid 13, is inserted.

25       In this step, the heads 59 of the mixing blades 57 abut against the piston 19.

The venting tube 34 is connected to a vacuum pump and operated.

By way of the rotation means (crank or motor), the pivot 24 is turned and consequently the piston 19 is turned together with the blades 57.

30       In this step, the locking element 55 is coupled to the annular groove

54, preventing the pivot 24 with the piston 19 from moving downward.

Once the mixing step produced by the rotation of the blades 57 has ended, the user detaches the locking element 55 and grips the pistol grip 41, beginning to press the lever 47 toward the bottom of the pistol grip 41.

5 This movement produces the downward advancement of the teeth 46, consequently pushing likewise downward the pivot 24 and therefore the piston 19.

By way of the leaf-spring element 50, the lever 47 is returned into position in order to allow to continue pushing the teeth 46 on the annular  
10 bulges 45, lowering the piston 19.

The fulcrum of the lever 47 is formed by a hinge that is constituted by a circular hole 47a, which is provided on the pistol grip 41 and in which there is a pivot (not shown in the figures) that is rigidly coupled to the lever.

In an alternative embodiment, the hole 47a has an oval shape, in  
15 which the corresponding major axis is substantially oriented along the extension of the pistol grip 41.

The piston 19 slides on the mixing blade 57 by way of the slots 58 and until it makes contact with the mixed paste.

At this point, the mixing chamber is a substantially airless and gas-  
20 free environment.

At this point, by again acting on the pistol grip, the formed paste is compressed, pushing it outward through the distribution channel 35 (the plug valve 38 has been opened beforehand).

In practice it has been found that the invention thus described solves  
25 the problems noted in known types of mixing and distribution device for multicomponent bone cement.

In particular, with the present invention there is no loss or leakage of toxic gas during the mixing of the components of the cement, since any gas is continuously aspirated during the mixing step.

30 The mixture is thus obtained in a practically airless environment, thus

avoiding the formation of air or gas bubbles.

Moreover, it is noted that all the cement that is obtained can be used, since the thrust of the piston 19 tends to push it out until it is depleted (the piston is shaped complementarily to the bottom of the receptacle 12).

5 The device is further compact and simple to use and handle.

In particular, by gripping it with a single hand one is able to direct the nozzle in the regions where the paste is to be distributed and to operate the mechanisms for distributing said paste.

Advantageously, the invention is substantially composed of two parts:  
10 a part that is provided in an already-assembled condition and comprises the lid with the handgrip, the pivot and the piston with mixing blades, and a part that relates to the box-like container inside which the paste is mixed.

In view of its limited structural complexity and of the fact that it is entirely made of plastic material, the device can be produced at extremely  
15 competitive costs and therefore used disposably.

The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the appended claims; all the details may further be replaced with other technically equivalent elements.

20 In practice, the materials employed, so long as they are compatible with the specific use, as well as the dimensions, may be any according to requirements and to the state of the art.

The disclosures in Italian Patent Application No. PD2003A000139 from which this application claims priority are incorporated herein by  
25 reference.